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Amendment
Attorney Docket No. S63.2B-9720-US01

Remarks

This Amendment After Final is in response to the Final Office Action dated December 2, 2004. In the Office Action, claims 64-66 were rejected under 35 USC § 112. Claims 1-9, 11-12, 14, 22, 25-26, 28-29 and 64-66 were rejected under 35 U.S.C. 102(e).

The paragraph numbers below correspond to those of the Office Action.

1. 35 USC § 112

Claims 64-66 were rejected under 35 USC § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "each inflatable member the inflatable members inflatable inward into the channel", is said to be unclear.

Claim 64 has been amended to correct a clerical error by deleting the phrase "each inflatable member". Withdrawal of the rejection is respectfully requested.

2-3. 35 USC 102

Claims 1-9, 11-12, 14, 22, 25-26, 28-29 and 64-66 were rejected under 35 U.S.C. 102(e) as being anticipated by Di Caprio et al. (US 6123712). The Office Action identifies references numerals 134, 144 or 139 as referring to inflatable members and maintains that the inflatable members of DiCaprio "are capable of inflating inward into the channel so as to reduce a cross section of the channel which extends perpendicular to a longitudinal axis of the channel."

Claim 1 and claims dependent therefrom

The Office Action provides no support from the patent for this assertion. The patent teaches that "balloon 134 is fluid inflated by standard technique to expand and deploy stent 142" (see col. 14, lines 5-6). Balloon 134 expands outward. Nowhere is there a teaching that the catheter of Di Caprio is configured such that during inflation of the balloon 134, pouch 138 is deformed inward or even a suggestion of such a modification. In fact, such a modification would arguably be undesirable in that it would likely result in uneven inflation of the stent which is disposed the balloon. If the Examiner considers the pouch to be part of the inflatable member, there is no teaching in Di Caprio, as discussed above, that the pouch would deflect inward on

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inflation of balloon 134. Therefore, claim 1 and claims dependent therefrom, which require a plurality of inflatable members which are inflatable inward, is patentable over Di Caprio.

Claims 2-4, 11-12 and 22, dependent from claim 1, are patentable over Di Caprio at least for the reason that claim 1 is patentable over Di Caprio.

Claim 3 is further patentable over Di Caprio at least because Caprio does not disclose the recited "at least three inflatable members".

Claim 11, dependent from claim 1, further recites that the plurality of inflatable members are disposed in one or more spirals about the channel.

The Office Action contends that "the plurality of inflatable members are disposed in one spiral about the channel (figs. 14-16)". This contention is erroneous. Figs. 14-16 show cross-sections of a tube and illustrates that the locations of the inflation ports vary about the length and circumference of the tube. Figs. 14-16 do not show inflatable members disposed in a spiral. For this additional reason, claim 11 is patentable over Di Caprio.

Claim 12, dependent from claim 1, further recites that the plurality of inflatable members includes at least two inflatable members which are circumferentially and axially displaced from one another.

Di Caprio does not disclose this feature. There is no teaching in Di Caprio that would indicate or suggest that the pouches and balloon of Di Caprio do not extend all the way around the circumference of the Di Caprio catheter tube. Therefore, Di Caprio lacks the recited inflatable members which are circumferentially offset from one another.

Claim 5 and claims dependent therefrom

Independent claim 5 includes the recitation that the inflatable members are inflatable from a first size to a second size in which the balloon contacting portions of the inflatable members apply an inward force to a balloon of a balloon catheter assembly disposed in the channel. The inflatable members are generally tubular and have a generally wedge shaped cross-section.

Di Caprio does not disclose this combination of features. The Office Action does not point out any balloon structure of Di Caprio that has the recited wedge-shaped cross-section. The Office Action also does not point out how balloon 134 of Di Caprio is capable of applying

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the required inward force to a balloon of a balloon catheter which is disposed in the channel. The material associated with balloon 134 would be expected to expand outward. Even if the Examiner considers pouch 138 to constitute an inner surface of balloon 134, there is no disclosure that the assembly would apply an inward force when an inflation fluid is directed into the balloon. Again, the balloon would expand outward, away from the catheter tube. Moreover, there is no disclosure of the Di Caprio catheter being configured so as to be capable of receiving a balloon associated with a balloon catheter within pouch 138.

At least for these reasons, claim 5 is patentable over Di Caprio.

Claim 6-9 and 28-30, dependent from claim 5, are patentable over Di Caprio at least for the same reasons that claim 5 is patentable over Di Caprio.

Claim 6 further recites the presence of a rigid tube in which the plurality of inflatable members are constrained where the tube has a first end with a first opening and a second end with a second opening and a passage therethrough.

The Office Action identifies tube 135 of Di Caprio.

Tube 135 of Di Caprio does not meet the claim limitation because the "inflatable members" identified in the Office Action are not constrained in the rigid tube, as required by claim 6. At least for this additional reason, claim 6, and claims 7-9 and 28-30 dependent from claim 6, are further patentable over Di Caprio.

Further as to claim 7 and claims 8 and 9 dependent therefrom, the Office Action contends that the segment 135 of Di Caprio constitutes an "end cap". Applicant disagrees. Segment 135 does not cap a rigid tube – it does not extend across an opening of a rigid tube as recited in the claim. Segment 140, likewise, does not extend across an opening of a rigid tube as recited in the claim.

Further as to claim 9, neither segment 135 nor segment 140 have an opening therethrough sized to receive at least a portion of a balloon catheter therethrough, as recited in claim 9.

Further as to claims 28-29, method claims which depend from claim 8, which in turn depends from claim 6, Di Caprio does not disclose at least partially deflating the medical balloon with the inwardly deformed portions of the medical balloon forming a plurality of balloon folds, as recited in these claims. Moreover, Di Caprio does not disclose removing the

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inflatable members from about the medical balloon. Doing this to the Di Caprio catheter would destroy the catheter. Di Caprio likewise does not disclose each of the balloon folds extending along the entire length of the balloon as recited in claim 29.

Therefore, at least for these additional reasons, claims 28-30 are further patentable over Di Caprio.

Claim 14

Independent claim 14 is directed to the combination of a device for configuring an inflatable balloon of a balloon catheter assembly and a balloon portion of a balloon catheter assembly. The claim includes the recitation that the device comprises a body comprising a plurality of inflatable members defining a channel therebetween. Moreover, the balloon portion of a balloon catheter assembly is disposed in the channel.

This limitation is not met by the Di Caprio catheter. Even if, for the sake of argument only, the Di Caprio catheter were to be considered as having the recited device (with the inflatable members defining a channel therebetween), Di Caprio, nevertheless, does not disclose the balloon portion of a balloon catheter disposed in the channel nor does Di Caprio suggest disposing the balloon portion of a balloon catheter in such a "channel". It would, in fact, be non-sensical to dispose a balloon catheter within the inner tube of Di Caprio. Therefore, claim 14 is patentable over Di Caprio.

Claim 25 and claims dependent therefrom

Claim 25 is directed to a method of configuring at least a portion of a medical balloon and includes several steps that are not disclosed by Di Caprio.

The claim includes the step of providing a device for configuring an inflatable balloon of a balloon catheter assembly. The device comprises a body comprising a plurality of inflatable members defining a channel therebetween, the channel sized to accommodate at least a portion of a balloon catheter, each inflatable member having a balloon contacting portion, the inflatable members inflatable from a first size to a second size in which the balloon contacting portions apply an inward force to a balloon of a balloon catheter assembly disposed in the channel.

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This step is not disclosed in Di Caprio. The Di Caprio catheter lacks inflatable members which inflate inward to apply an inward force to a balloon of a balloon catheter. As discussed above, if the pouches of Di Caprio are not part of what the Examiner considers to be the "inflatable member", then it is not seen how balloon 134 of Di Caprio can inflate inward. If the pouches are part of the "inflatable member", there is a) nevertheless no disclosure that these structures inflate inward – to the contrary, they would be expected to inflate outward, and b) the pouches do not apply a force to a balloon, as required by the claim.

Di Caprio also lacks the recited steps of disposing a medical balloon between the inflatable members and at least partially inflating the medical balloon.

Moreover, Di Caprio lacks the recited step of inflating the inflatable members so that the balloon contacting portions deform portions of the medical balloon inward.

Finally, Di Caprio lacks the step of at least partially deflating the medical balloon, the inwardly deformed portions of the medical balloon forming a plurality of balloon folds; and removing the inflatable members from about the medical balloon. First, Di Caprio does not disclose forming balloon folds in the manner recited in the claim. Second, to the extent, for the sake of argument only, that the inflatable members are the structures identified by the Office Action, nowhere does Di Caprio disclose removing them from the catheter. Such an action would destroy that catheter.

At least for these reasons, claim 25 is patentable over Di Caprio.

Claim 26 depends from claim 25 and is patentable over di Caprio at least for the reasons discussed above with respect to claim 25.

Claim 26 further recites that each of the balloon folds extends along the entire length of the balloon. Di Caprio does not disclose such a feature, thus providing a further ground for patentability over Di Caprio.

Claim 64 and claims dependent therefrom

Claim 64 is directed to a device for configuring an expandable member for use in a bodily vessel. The device comprises a body comprising a plurality of inflatable members defining a channel therebetween. The channel is sized to accommodate at least a portion of the expandable member. The inflatable members are inflatable inward into the channel so as to

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reduce in area a cross-section of the channel which extends perpendicular to a longitudinal axis of the channel.

Di Caprio does not disclose the features of claim 64 and claims 65-66 dependent therefrom. To the extent that the Examiner were to consider members 134 by themselves as constituting the recited inflatable members, members 134 do not inflate inward. To the extent that the Examiner considers members 134 in conjunction with pouches 138 to constitute the recited inflatable members, again, there is no teaching that they would inflate inward. To the contrary, one would expect the combination to expand outward as well. If they expanded inward even as they expanded outward, one would expect the resulting expansion of the stent to be non-uniform.

Claim 65 and claim 66 dependent therefrom further recite that the body further comprises a rigid tube in which the plurality of inflatable members are constrained, the tube having a first end with a first opening and a second end with a second opening and a passage therethrough. As discussed above with respect to claim 6, Di Caprio does not disclose the rigid tube in which inflatable members are constrained. Therefore, for this additional reason, claims 65 and 66 are patentable over Di Caprio.

In light of the above comments, withdrawal of the rejection is respectfully requested.

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Conclusion

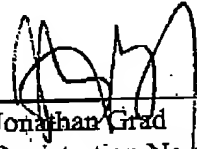
In light of the above comments, the pending claims, including withdrawn claims are believed to be in condition for allowance. Notification to that effect is respectfully requested.

Respectfully submitted,

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Date: February 2, 2005

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